82D CONGRESS
1st Session
HOUSE OF REPRESENTATIVES
REPORT
No. 700

AMENDING SECTION 503 (b) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

JULY 16, 1951.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. WILLIAMS of Mississippi, from the Committee on Interstate and Foreign Commerce, submitted the following

REPORT

[To accompany H. R. 3298

The Committee on Interstate and Foreign Commerce, to whom was referred the bill (H. R. 3298) to amend section 503 (b) of the Federal Food, Drug, and Cosmetic Act, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

The amendment is as follows:

Strike out all after the enacting clause and insert the following:

That subsection (b) of section 503 of the Federal Food, Drug, and Cosmetic Act, as amended, is amended to read as follows:

"(b) (1) A drug intended for use by man which—

"(A) is a habit-forming drug to which section 502 (d) applies; or

"(B) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, has been determined by the Administrator, on the basis of opinions generally held among experts qualified by scientific training and experience to evaluate the safety and efficacy of such drug (and, where a public hearing is required by paragraph (5), on the basis of evidence adduced at such hearing by such experts), to be safe and efficacious for use only after professional diagnosis by, or under the supervision of, a practitioner licensed by law to administer such drug; or

"(C) is limited by an effective application under section 505 to use under the professional supervision of a practitioner licensed by law to administer such drug,

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

"(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the

requirements of section 502, except paragraphs (a), (i) (2) and (3), (k), and (l), and the packaging requirements of paragraphs (g) and (h), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail or otherwise without examination of the patient or to a drug dispensed in violation of paragraph (1) of this subsection.

"(3) The Administrator may by regulation remove drugs subject to section 502 (d) and section 505 from the requirements of paragraph (1) of this subsection when such requirements are not necessary for the protection of the public health.

"(4) A drug which is subject to paragraph (1) of this subsection shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement 'Caution: Federal law prohibits dispensing without prescription'. A drug to which paragraph (1) of this subsection does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the caution statement quoted in the preceding sentence or any other statement which represents or implies that the dispensing of the drug without the prescription of a licensed practitioner is prohibited.

"(5) Any interested person may file with the Administrator a petition proposing the making of a determination, or the modification of a determination made or proposed to be made, by the Administrator pursuant to subparagraph (B) of paragraph (1). The filing of a petition for the purpose of opposing a proposed determination that a drug is one to which such subparagraph (B) applies shall stay the operation of paragraph (1) with respect to such drug until a petition for judicial review can be filed and interim relief sought under section 10 (d) of the Administrative Procedure Act. The petition shall set forth in general terms the proposal contained therein, and shall state reasonable grounds therefor. The Administrator shall give public notice of the proposal made in the petition and shall give to all interested persons a reasonable opportunity to present their views thereon, orally or in writing, and as soon as practicable thereafter shall make public his action on the proposal. At any time prior to the thirtieth day after such action is made public, any interested person may file with the Administrator objections to such action, specifying with particularity the changes proposed, stating reasonable grounds therefor, and requesting a public hearing for the taking of evidence of experts who are qualified by scientific training and experience to testify on the question of whether the drug in question is safe and efficacious for use only after professional diagnosis by, or under the supervision of, a practitioner licensed by law to administer such drug. The Administrator shall thereupon, after appropriate notice, hold such public hearing. As soon as practicable after the hearing, the Administrator shall make his determination and issue an appropriate order. The Administrator shall make his order only after a review of the whole record and in accordance with the reliable, probative, and substantial evidence, and shall make detailed findings of the facts on which he based his order. Such order shall be subject to judicial review in accordance with the provisions of section 701 (f) and (g).

"(6) Nothing in this subsection shall be construed to relieve any person from any requirement prescribed by or under authority of law with respect to drugs now included or which may hereafter be included within the classifications stated in section 3220 of the Internal Revenue Code (26 U. S. C. 3220), or to marihuana as defined in section 3238 (b) of the Internal Revenue Code (26 U. S. C. 3238 (b))."

SEC. 2. The provisions of this Act shall take effect six months after the date of its enactment.

WHAT THE BILL DOES

This bill amends the Federal Food, Drug, and Cosmetic Act to accomplish two broad objectives:

(1) To strengthen the protection of the public health against dangerous abuses in the sale of potent prescription drugs;

(2) To relieve retail druggists and the public from burdensome and unnecessary restrictions on the dispensing of drugs which may be safely used without supervision by a physician.

The bill does this by placing in the Federal Food, Drug, and Cosmetic Act express provisions which will eliminate confusion and dissatisfaction which exist under the present rather general provisions dealing with the labeling and dispensing of drugs which may be sold only on prescription and drugs which may be sold over the counter.

The bill, as amended, is designed to solve these labeling and dispensing problems in the following ways:

1. By providing for a clear-cut method of distinguishing between "prescription" drugs (that is, drugs which are not suitable for self-medication because they should be used only under the supervision of a physician, and which therefore should be dispensed only on prescription) and "over-the-counter" drugs (that is, drugs which are suitable for self-medication, and which therefore should be permitted to be dispensed freely "over-the-counter"), and by requiring that drugs be so labeled as to indicate to the retail druggist and to the general public into which of these two classes they fall.

Under the present law, and the regulations issued thereunder, the initial responsibility is upon the manufacturer to decide whether his drug is unsuitable for self-medication and therefore must be labeled with a caution legend (that is, a warning that the drug in question may be dispensed only by or on prescription of a physician) and may be sold only on prescription, or whether his drug is suitable for self-medication and therefore must be labeled with adequate directions for use and may be sold freely over the counter. Lack of uniformity among manufacturers in interpreting the present law and regulations has led to great confusion in the labeling of drugs for prescription sale and for over-the-counter sale.

2. By expressly setting forth in the statute the restrictions applicable to the dispensing of "prescription" drugs.

At present the restrictions on dispensing "prescription" drugs are not specifically stated in the statute. As hereafter explained, they result from conditions which have been imposed by the Federal Security Administrator in connection with certain exemptions which he is authorized to grant under the present law.

3. By authorizing the filling and refilling of telephone prescriptions under appropriate safeguards.

The present law recognizes written and signed prescriptions only, in complete disregard of the need for the use of the telephone in prescribing medicines.

4. By specifying in detail the conditions under which pharmacists may refill prescriptions.

Under the present law no prescription may be lawfully refilled unless refilling is specifically authorized in writing by the prescribing physician. This makes it unlawful for the pharmacist to refill prescriptions without written authorization even for drugs which are suitable for self-medication. The bill would permit the refilling of prescriptions for such drugs without authorization from the physician. However, in the case of dangerous drugs, habit-forming drugs, and new drugs which are limited to use under medical supervision, it would prohibit refilling unless the prescribing physician specifically authorizes the refill.

Committee Hearings

The committee held extensive hearings on this bill. The testimony amply supports the conclusion that legislation is urgently needed and it is believed that the provisions of the bill, as amended, will further the protection of the public health by meeting the complex problems which were brought to the committee's attention in the hearings.

The committee has received communications with respect to this proposed legislation from the Federal Security Administrator, the Deputy Attorney General, and the Administrative Office of the United States Courts. These communications are printed in an appendix to this report.

General Statement

Prescription drugs.—There is urgent need for affirmative and clear provisions in the law to deal with the labeling of prescription drugs and the restrictions upon their sale.

The present law prohibits the over-the-counter sale of drugs labeled as being for prescription sale only, but it does this in the following indirect manner.

A drug is required by present law to bear "adequate directions for use." This requirement may be relaxed by regulations of the Federal Security Administrator when such directions are not necessary for the protection of the public health. Drugs suitable for use only by or under the direction of a licensed practitioner have been exempted from the adequate directions requirement on condition that they be labeled "Caution—To be dispensed only by or on prescription of a physician." If a druggist sells without a prescription a drug bearing this caution label, the drug is misbranded and the druggist violates the act.

The present law and regulations do not provide a satisfactory method for determining the drugs which properly fall within the prescription class. Furthermore, these matters should be regulated by specific statutory provisions rather than, as at present, largely through administrative regulations.

Under the present regulation the retail druggist is often unable to know, until the question is settled by litigation, whether a particular drug can be sold on prescription only. The regulation requires the prescription legend on drugs which are generally regarded as safe and efficacious for use only under medical supervision. All other drugs are required to bear adequate directions for use, and this means directions adequate for a layman to follow. The initial responsibility is upon the manufacturer to decide whether his drug belongs in one class or the other.

If a manufacturer decides that his drug is suitable for use only under medical supervision, and labels it with the prescription legend, it is necessary, if the Administrator disagrees on the basis of expert advice to that effect, to bring a criminal prosecution, a seizure action, or an injunction to require that the legend be taken off and adequate directions for use written. On the other hand, if the manufacturer decides that his drug is suitable for use by a layman without consulting a physician, and labels it with directions for use, but the Administrator disagrees on the basis of expert advice to that effect, an action must be

brought charging that the drug violates either section 502 (a) by being represented falsely to be safe and effective for lay use or section 502 (j) because the drug may be dangerous to health when used as directed. Litigation, at best, is a slow process and can be directed at only one party and one product at a time. It is not a satisfactory method for establishing correct future labeling of a particular drug regardless of who manufactures it.

The practical effect of the present regulatory system has been great confusion in the use of the prescription legend. Many products of identical composition, placed on the market by different manufacturers, were shown to the committee in a practical demonstration of the druggists' dilemma. One would bear the prescription legend while another of the same composition would provide directions for use.

For example, a sample of precipitated chalk manufactured by one manufacturer was labeled with the legend:

Caution: To be dispensed only by or on the prescription of a physician, dentist, or veterinarian, or otherwise used only for manufacturing purposes. This restriction applies only to medicinal uses.

Another sample of the same drug manufactured by a different manufacturer carried the following directions for use:

Antacid—Average dose: one-quarter teaspoonful in water. May also be used as a tooth powder.

Another example involved strychnine sulfate in small doses (one-sixtieth grain). This drug manufactured by one manufacturer carried the legend:

Caution: To be dispensed only by or on the prescription of a physician.

The same drug manufactured by another manufacturer carried the following directions for use:

To improve appetite and digestion. For adults only: 1 tablet before meals. Other doses as prescribed by physician. Warning: Do not take more than 6 tablets in 24 hours.

A third example involved dehydrocholic acid. This drug manufactured by one manufacturer carried the caution legend:

To be used only by or on the prescription of the physician.

The identical drug produced by another manufacturer carried the following directions for use:

Dosage: *Adults*—1 tablet 3 times daily with or after meals. *Children*—Only under the direct supervision of a physician.

In the presence of jaundice, this product should be used only under the direction of a physician.

It should be noted that these directions for use do not state the condition for the treatment of which this particular drug is to be used.

Also presented were samples of acetophenetidin and acetophenetidin with salol which, as manufactured by one manufacturer, carried the caution legend, and as manufactured by another manufacturer carried directions for use.

Some products were shown to the committee which had something like the prescription legend and also recommended dosages. The druggist would not even know, in such a case, the class in which the manufacturer intended to place such drugs.

For example, in the case of ammonium chloride (7½ grains), one manufacturer labeled this drug with a caution legend:

Caution: To be dispensed only by or on the prescription of a physician.

The same drug manufactured by another manufacturer carried the following legend:

Adult dose—one or two tablets repeated as directed by the physician.

A second sample involved thyroid tablets. One manufacturer labeled this drug:

Caution: To be dispensed by or on the prescription of a physician. Indiscriminate use may be harmful.

Another manufacturer labeled the identical drug as follows:

Directions: To be used on advice or prescription of a physician.

It should be noted that while the "directions" refer to prescription of a physician, confusion is caused to the druggist by failing to use the standard caution legend prescribed by the regulations.

A third example involves quinidine sulfate. One manufacturer labeled this drug with the standard caution legend:

Caution: To be dispensed only by or on the prescription of a physician.

Another manufacturer labeled the same product with the following legend:

Adult dose—1 tablet as directed by the physician.

An example of three different labels for the same drug was also presented. Methenamine was labeled by the first manufacturer:

Adult dose—1 to 3 tablets as directed by the physician.

The second manufacturer labeled this product:

Caution: To be used only by or on the prescription of a physician.

The third manufacturer labeled this drug with the following directions for use:

Dose: As a urinary antiseptic, 1 tablet with a large glass of water twice a day for not longer than 7 days. Urine should be kept acid. Other dosage or uses as directed by physician.

The confusion existing under present law has resulted in inadequate protection of the public health. In a situation where the druggist is uncertain as to the drugs which may be dispensed only on prescription, it is inevitable that there have been many cases of indiscriminate and unauthorized over-the-counter sales of dangerous drugs and other drugs which should be used only under medical supervision.

The committee believes that the present public health problem in connection with the unlawful labeling and dispensing of prescription drugs exists largely because the present law is not clearly and affirmatively expressed in the statute. The overwhelming majority of drug manufacturers and pharmacists are anxious to comply with provisions of law which they can understand. In contrast with the present law, this proposed legislation will be clear and readily understood. It is believed that after this legislation is enacted the need for enforcement, through criminal action, seizure, and injunction, will arise only in the cases of a few violators who are oblivious to their obligations to society.

Under the bill, as amended, three types of drugs will be limited to prescription sale, namely, habit-forming drugs, "dangerous" drugs,

and new drugs which, under the present law, already may be limited to use under professional supervision. The confusion under present law exists primarily with respect to "dangerous" drugs, that is, those not suitable for self-medication. The bill provides a workable method by which clear determinations can be made, at the earliest practicable time, as to whether particular drugs are "dangerous" drugs. Such determinations will be made by the Federal Security Administrator on the basis of a statutory standard, and a list of such drugs will be formulated. The Administrator's determinations will be subject to judicial review.

All drugs which, by the amended bill, are restricted to prescription sale *must* carry the prescription legend: "Caution—Federal law prohibits dispensing without prescription." No other drugs will be permitted to carry this prescription label. The latter drugs, as required by the present law, must carry adequate directions for use telling the user what the drug is for and how it is to be used.

The bill, as amended, expressly provides that the drugs limited to prescription sale (when intended for human consumption) shall be dispensed only upon a written or oral prescription of a licensed practitioner. Oral prescriptions will be permissible only when promptly reduced to writing by the pharmacist and filed by him. Refilling of prescriptions will be permissible only if authorized in the original prescription or by an oral order of the licensed practitioner which is promptly reduced to writing by the pharmacist and filed by him.

This legislation will provide for certainty which is lacking under the present law and which is very important to the enforcement agency, to the retail druggist, and to the public. The committee believes that these changes in the law will impose no hardship on the reputable manufacturer and will, indeed, afford him a means of knowing, before he subjects his products to seizure and himself to prosecution, whether his drug must be labeled for prescription dispensing or for over-the-counter sale.

Certainty is important to the enforcement agency because it permits more effective enforcement through appropriate control over drugs that are too dangerous, or otherwise unsuitable, to be used by a layman without medical diagnosis or supervision. Under this proposed legislation it will be possible to *prevent* injury to the public, as contrasted with the present system which is largely concerned with punishing past violations.

Oral prescriptions.—Another phase of the present law which needs modification and clarification is with respect to the filling and refilling of oral, or telephone, prescriptions. The present law does not recognize the practice of dispensing drugs on oral prescription. For the convenience of the public, the retail druggist, and the physician, the committee feels that the filling and refilling of prescriptions on oral order, under proper safeguards, should be permitted. The bill, as amended, contains appropriate provisions, explained below in this report, which deal with this question.

Refilling prescriptions.—The Food and Drug Administration has found that a serious public-health problem exists in the indiscriminate refilling of prescriptions for dangerous and habit-forming drugs. Examples were cited in which death resulted from unauthorized refillings of prescriptions for barbiturates and benzedrine. A 45-year-old man, father of two children, was found dead in 1950 from an overdose of barbiturates obtained on a prescription written in 1945

or 1946. Investigation revealed that the original prescription had been refilled many times without consulting the prescribing physician. The man became addicted to this habit-forming drug and shortly before his death was taking many times the therapeutic dose to satisfy his cravings. His death would not have occurred had the physician's instructions been followed.

The benzedrine death occurred in 1950, 13 years after the original prescription was written. The widow stated that the prescription had been repeatedly refilled during that time. The physician had last seen the deceased in 1937 and at that time had written a prescription for 14 10-milligram tablets. The amount dispensed in the refills had substantially increased until just before his death this man was taking as much as 25 tablets a day. The prescribing physician stated that he had not intended that the patient take more than the original 14 tablets which he prescribed.

The Food and Drug Administration has interpreted the existing law to prohibit the unauthorized refilling of prescriptions for all drugs. This interpretation, which is doubtless justified by the terms of the present law, is needlessly restrictive in making illegal the refilling of prescriptions for those drugs that can be bought over the counter without prescriptions. Furthermore, it is difficult for the enforcement official to meet the refill problem as it relates to dangerous and habit-forming drugs when that matter is not expressly dealt with in the statute.

The committee has included in the bill, as amended, express provisions, explained below in this report, to clarify the present law with respect to the refilling of prescriptions.

Determination of What Drugs Are Prescription Drugs

CONFLICTING LEGISLATIVE RECOMMENDATIONS

The committee was confronted with a dilemma in that the trade and professional organizations representing the different interested groups have made conflicting recommendations. The National Association of Retail Druggists, on the one hand, has urged that in the interest of achieving the greatest possible certainty for the retail druggists and the general public, the Federal Security Administrator should be vested with the power to determine on the basis of a statutory standard, but subject to judicial review, which drugs are to be sold on prescription only. The drug manufacturers, on the other hand, represented by the American Pharmaceutical Manufacturers' Association, the American Drug Manufacturers' Association, and the Proprietary Association, and those pharmacists who are represented by the American Pharmaceutical Association, have opposed the vesting of any such authority in a Federal official. They have contended that the determination of which drugs may be sold only on prescription should be left to judicial determination, on the basis of a statutory standard, in court proceedings (seizure, criminal prosecution, or injunction) instituted by the Federal enforcement officials.

THE COMMITTEE'S DECISION

The committee has thoroughly studied the arguments adduced by both sides in favor of their respective proposals. It has come to the conclusion that administrative determination, subject to judicial

review, gives the greatest promise of effectively relieving the retail druggists and the general public from the presently existing confusion. This decision has been made somewhat reluctantly because the committee is deeply conscious of the fact that the power to determine which drugs are prescription drugs and which are over-the-counter drugs is one which affects drug manufacturers, drug wholesalers, retail druggists, pharmacists, physicians, and, last but not least, the general public. The reasons for the committee's decision are set forth below.

PROPOSED STATUTORY LIST

The committee studied the question of whether such a grant of power to an administrative officer could be avoided by inserting in the bill a list of drugs that may be sold on prescription only. The committee, however, has come to the conclusion that such a list could be formulated only after extensive hearings involving expert testimony with respect to each drug that might be placed on this list. Furthermore, over the years, a statutory list of prescription drugs would prove too inflexible to keep pace with the rapid changes and developments occurring in the drug field.

CASE-BY-CASE JUDICIAL DETERMINATION

The committee gave careful consideration to the proposal of the drug manufacturers that the determination of which drugs may be sold only on prescription should be left solely to judicial determination in seizure, injunction, and criminal cases.

Testimony was presented that this case-by-case method of judicial determination would unnecessarily and unfairly involve retail druggists in court proceedings. This would come about, so the retail druggists argue, because the Federal Security Administrator would continue to have the power, which he now has and which he now exercises, to seize drugs on the shelves of retail druggists (or to institute injunction or criminal proceedings against druggists) primarily for the purpose of bringing test cases to determine whether the drugs in question are prescription drugs or over-the-counter drugs. Not infrequently, unfavorable publicity results from such seizures or court proceedings to the great damage of the druggist, injuring him not only financially but also lowering his standing in the community.

The committee feels that the institution of test cases to determine for the future whether a given drug may be sold only on prescription or may be sold over the counter does not constitute a desirable and effective use of the judicial process. Actually, in such cases, the Government would not be seeking primarily the decision of the court that a particular person had violated the law. It would be seeking a determination of the court that drug "A," for example, is too dangerous for self-medication, and that, therefore, in the future, it should be sold only on prescription, or conversely, that drug "B" which was labeled with the prescription legend, and which failed to set forth on its label proper directions for use, was actually a safe drug which could be sold over the counter.

CONSIDERATIONS WHICH INFLUENCED THE COMMITTEE'S DECISION

The considerations which have influenced the committee in its decision to provide for administrative determination subject to judicial review may be summarized as follows:

First. The administrative process will involve as parties only those primarily interested, namely, the drug manufacturers. It would not involve the retail druggists, whose interest is limited to securing certainty as to how they may sell a given drug.

Second. The task of determining which drugs shall be sold only on prescription is, in its nature, essentially a legislative or rule-making function, unsuited for solution solely through the judicial process.

Third. The committee's decision is entirely consistent with the one made in 1938 when Congress gave the Administrator the authority to list habit-forming derivatives of the drugs named in section 502 (d), and it has not been suggested that that authority has been abused.

Fourth. In the opinion of the committee the judicial-review provisions afford adequate protection against arbitrary or legally unjustified action on the part of the Administrator. This particular phase is discussed below in greater detail under the heading "Judicial review."

Fifth. If the proposal of the drug manufacturers were adopted, great confusion might result from conflicting court decisions with respect to the same drug in different jurisdictions. One United States district court might hold that a given drug was dangerous, judged by the statutory standard, while another district court might hold the opposite. There are more than 80 United States district courts. Even if all of the cases were tried without juries, it would be almost beyond the realm of possibility that uniformity could be obtained. With the vagaries of the jury system, it is believed that uniformity of decisions would be wholly impossible. One firm might obtain a judgment favorable to it that a particular drug was safe for over-the-counter sale, while others in the industry were required to limit it to prescription sale.

From a public-health standpoint, the users of drugs should not be subjected to the hazards of delay incident to litigation. A recent hormone case, decided in favor of the Government by the United States Court of Appeals for the Ninth Circuit, took more than 2 years in litigation in order to limit the drug to prescription use under existing law. The drug was capable of causing accelerated growth of cancer of the prostate, a condition not uncommon in the fifties and sixties. While the litigation was in progress irreparable injury was done. Under the suggestion to use the case-by-case method of judicial determination, the druggist, on whom the burden of prosecution would fall most directly, would be in a very difficult position. He would have to determine at his risk whether a drug which the manufacturer had labeled with directions for use for over-the-counter sale had been correctly classified. He would follow the label only at his peril.

Finally, it is difficult to understand why the drug manufacturers themselves should prefer to have their products seized or to be proceeded against in criminal cases merely toward the end of securing a determination as to whether a particular drug is or is not a prescription drug.

LIMITATIONS ON ADMINISTRATOR'S POWERS

The committee recognizes that the Federal Security Administrator is not, and should not be expected to be, an expert qualified to decide which drugs should be sold on prescription only and which should be sold freely over the counter. Therefore, in the bill, as amended, the committee has provided that the Administrator is to make this determination on the basis of a statutory standard. The standard which he is to apply is essentially the same standard presently contained in the regulations of the Federal Security Administrator promulgated under section 502 (f) of the Federal Food, Drug, and Cosmetic Act. That standard has been accepted by the drug trade as proper and adequate, and representatives of drug manufacturers, appearing before the committee, urged that it be written into the law as the basis for case-by-case judicial determinations.

Under this standard a drug will be adjudged a prescription drug if because of its toxicity or any other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, it is unsafe or inefficacious for use without professional supervision. In applying this standard to a given drug, the Administrator is directed to follow the opinions generally held among experts qualified by scientific training and experience to evaluate the safety and efficacy of the drug in question. If any interested party desires a public hearing on whether a particular determination by the Administrator on that basis is justified, he may demand such a hearing. At the hearing the evidence taken will be evidence presented by qualified experts. The Administrator must base his action, after the hearing, on the testimony given by such experts, not on his own personal views. In short, the committee amendment, in effect, places the Federal Security Administrator in the role of collecting informed medical opinions and, in either placing the drug on the prescription list or deciding that the drug is suitable for over-the-counter sale, he merely reflects the opinions generally held among medical experts.

By incorporating this standard in the law and by specifying the process to be used by the Administrator in applying it, the committee believes it has achieved a practical and equitable solution of the dilemma in which it found itself as a result of the conflicting legislative recommendations submitted by the trade and professional organizations in the drug field.

EFFICACY OF DRUGS

The standard which the bill, as amended, would write into the law (subparagraph (B) of paragraph (b) (1) of the amendment) contains the words "efficacy" and "efficacious." The use of these words has given rise to some apprehension, particularly on the part of manufacturers of proprietary drugs (patent medicines), that the Federal Security Administrator might have the power to determine which drugs are "efficacious" or "effective" and which are not. It may be stated unequivocally that this provision is not intended to grant any such power to the Administrator, nor does it lend itself in any way to such an interpretation.

The provision provides for a determination by the Administrator whether a given drug—

on the basis of opinions generally held among experts qualified by scientific experience to evaluate the safety and *efficacy* of such drugs * * * [is] * * * safe and *efficacious for use only after professional diagnosis by, or under the supervision of, a practitioner licensed by law to administer such drug;* * * *.

The question to be determined by the Administrator on the basis of expert opinion, therefore, is not whether a drug is efficacious but whether it can be used efficaciously without professional diagnosis or supervision.

The provision assumes that the drug is effective in the hands of a physician, and the reason for putting it on the prescription list is that it is only effective when used under professional supervision.

For example, no qualified person questions the efficacy of quinidine sulfate in the treatment of certain heart diseases. However, in view of the serious nature of the disease and the necessity of adjusting the dose to the individual patient's need, the drug obviously cannot be used with efficacy except when used under professional supervision. While the drug is not dangerously toxic, the user may nevertheless die if in the course of self-medication he should fail to take a dose which is suited to his individual needs.

JUDICIAL REVIEW

A determination by the Administrator, though based on expert testimony, will be reviewable by the courts. By making applicable the provisions of section 701 (f) and (g) of present law, the amended bill will insure that any interested person may obtain judicial review by a United States court of appeals and, upon certiorari, by the Supreme Court of the United States.

The reviewing court will have power to set aside the Administrator's order if it is not in accordance with law, and the Administrator's findings as to the facts will be conclusive only if supported by reliable, probative, and substantial evidence on the record considered as a whole.

The bill, as introduced, proposed to permit any interested person dissatisfied with a determination of the Administrator to secure judicial review in the nature of a trial de novo in a court of appeals of the United States. This provision was intended to give to an aggrieved party the greatest possible insurance of fairness and justice. However, the committee is convinced that no matter how well intended, this proposal was impractical.

The committee came to this conclusion largely on the basis of the very earnest presentation made by the Honorable Harold M. Stephens, Chief Judge of the United States Court of Appeals for the District of Columbia Circuit, speaking on behalf of, and by direction of, the Judicial Conference of the United States. The gist of Judge Stephens' testimony was that the needs of the United States courts demand that the judicial review of administrative determinations be limited to a review of whether the administrative determination is based on reliable, probative, and substantial evidence considering the whole record made before the administrative agency. This is the extent and character of review provided for under the provisions of the Administrative Procedure Act, enacted in 1946.

It was pointed out by Judge Stephens that the United States courts of appeals are appellate courts and not trial courts, and that such courts for several reasons are not equipped to handle trials. First, the United States courts of appeals are three-judge courts. It has been the experience of the United States courts that trials are conducted more efficiently by single judges than by three or more judges. Questions involving the admissibility of evidence, for example, have to be determined frequently and promptly in the course of a trial. While a single judge can rule on these questions as they occur without delay, three judges would have to confer on each issue as it was raised and such conferences involve necessarily delay, thus making the trial a cumbersome affair. Furthermore, United States courts of appeals, being appellate courts rather than trial courts, do not have jury boxes in their courtrooms, do not have jury lists, and do not have jury rooms. All of these considerations militate against providing for de novo trials in United States courts of appeals.

If, on the other hand, the district courts of the United States were to be required to determine the validity of administrative determinations in all instances on the basis of de novo trials, such a great additional burden would be placed upon these courts that the number of Federal district court judges would have to be greatly increased.

Furthermore, Judge Stephens pointed out with great emphasis that recent decisions of the Supreme Court of the United States (*Universal Camera Corp.* v. *N. L. R. B.* and *Labor Board* v. *Pittsburgh S. S. Co.*, decided February 26, 1951) insure that the ordinary and usual type of judicial review of administrative action (which is the type provided for by this bill, as amended, and by the Administrative Procedure Act) affords full protection against arbitrary or legally unjustified action by administrative officials.

In addition to the foregoing objections to the proposal to provide for judicial review in a trial de novo, it is believed that the proposal might be unconstitutional on the ground that it would seek to have Federal "constitutional" courts exercise a function which is essentially legislative or administrative, rather than judicial. This point is discussed in the letters from the Deputy Attorney General and the Federal Security Administrator printed in the appendix to this report.

Oral Prescriptions

The bill, as amended, contains provisions which give statutory recognition to the frequent practice engaged in by physicians of using the telephone to transmit prescriptions to a pharmacist. The use of the telephone in prescribing medicines is of great convenience to the users of such medicines and is, in some areas of this country, essential to the public health. The statutory recognition of oral prescriptions proposed by the bill does away with the unrealistic provisions of the present Federal Food, Drug, and Cosmetic Act which recognizes a written and signed prescription only. The committee amendment would permit the use of oral prescriptions in the case of all drugs. However, in case of habit-forming drugs, dangerous drugs, or new drugs which are limited to prescriptions, an oral prescription would have to be reduced promptly to writing and filed by the pharmacist.

The committee gave serious consideration to whether it was desirable to place additional safeguards on oral prescriptions. However, it was determined that the admittedly limited safeguards provided for in the committee amendment would be adequate until the need for more rigid requirements has been proven by experience.

If the committee amendment is enacted into law, it is hoped that the Commissioner of Food and Drugs will observe closely the effect of the provisions with respect to oral prescriptions and will report to the responsible committees of both Houses any abuses that might develop as a consequence of the relaxation of the written prescription requirement now contained in the Federal Food, Drug, and Cosmetic Act.

Refilling Prescriptions

The bill, as amended, deals expressly with the troublesome problem of refilling prescriptions. Under the present law a drug dispensed on a "written prescription, signed by a physician," is entitled to certain limited exemptions from the labeling requirements that ordinarily apply to drugs. Through the force of these exemptions, drugs sold on written prescriptions are not misbranded even though they fail to meet the labeling requirements of the act. The Food and Drug Administration, relying upon its understanding of what is meant by a "written prescription," has taken the position that a drug dispensed by refilling a prescription without the knowledge or consent of the prescriber is not dispensed on prescription and thus is not exempt from the labeling provisions of the act. Without such exemption, the drug is misbranded by dispensing it without the prescriber's authorization.

This administrative position meets the public health problems found to exist by reason of the indiscriminate and unauthorized refilling of prescriptions for dangerous drugs and for other drugs that require medical supervision for their effective use. Some drugs, such as amphetamine (benzedrine) and the barbiturates, are desired by addicts and others for nonmedical use. The records of the Food and Drug Administration contain the stories of broken homes and human derelicts that the improper use of these drugs has caused. Other drugs in the prescription-only class may cause irreparable injury before the user knows that the drug is having any physiological effect upon him. But the present law, interpreted to reach these abuses existing in connection with the refilling of prescriptions, also prohibits the refilling of prescriptions for drugs that are not dangerous and are entirely suitable for use by a layman without medical supervision. Furthermore, if the refilling of prescriptions for dangerous drugs and drugs which require medical supervision in their use is to be controlled, the statute itself should contain express provisions providing for such controls.

The bill, as amended, meets this situation by providing that when drugs are prescribed which are safe and effective for lay use without medical supervision, and which could be bought freely over the counter without a prescription, the prescriptions may be freely refilled. But as to drugs which are habit-forming, or which are safe and efficacious only after medical diagnosis has been made or when medical supervision is exercised, and as to drugs which are restricted by new drug applications to use under medical supervision, the bill provides that

prescriptions cannot be refilled unless the prescriber has expressly authorized the refill. This authorization may be either written or oral, but if it is given orally the dispenser must promptly reduce the authorization to writing and file it.

Section by Section Explanation of the Bill, as Amended

SECTION 1. AMENDMENT TO EXISTING LAW

The first section of the bill, as amended, proposes to rewrite section 503 (b) of the present law. At the present time, section 503 (b) merely provides for an exemption from certain labeling requirements in the case of drugs dispensed on written prescription. As proposed to be rewritten, section 503 (b) would contain paragraphs (1) to (6), inclusive, which are explained below:

Paragraph (1)—Prohibited acts

This paragraph provides that three types of drugs which are intended for human consumption shall be dispensed only under the following conditions:

(i) Upon a written prescription of a practitioner licensed by law to administer the drug, or

(ii) Upon an oral prescription of such practitioner which is reduced promptly to writing by the pharmacist and filed by him, or

(iii) By refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by an oral order which is reduced promptly to writing by the pharmacist and filed by him.

The types of drugs to which these requirements are made applicable are specified in three subparagraphs, designated (A), (B), and (C).

Subparagraph (A) covers habit-forming drugs. Subparagraph (C) covers any new drug which, under other provisions of the act, is limited to use under professional supervision. No controversy has arisen as to these provisions.

Subparagraph (B) covers "dangerous" drugs, and describes them as any drug which—

> because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, has been determined by the Administrator * * * to be safe and efficacious for use only after professional diagnosis by, or under the supervision of, a practitioner licensed by law to administer such drug.

The standard here used is essentially the same as that used in regulations heretofore prescribed under the act. As used in such regulations the standard has been generally acceptable to the drug industry as shown in the testimony before the committee.

Subparagraph (B) provides that the Federal Security Administrator will have the duty of determining (on the basis of opinions generally held among qualified experts) the specific drugs covered by the standard, his determination being subject to judicial review as provided in paragraph (5).

Paragraph (1) provides that the act of dispensing a drug contrary to its provisions shall be deemed to be an act which results in the drug being misbranded while held for sale. The effect of this provision is to

make criminal, injunction, and seizure provisions of the act applicable to the dispensing of a drug in violation of the provisions of paragraph (1).

Paragraph (2)—Exemption from labeling requirements

This paragraph exempts drugs dispensed by filling or refilling a written or oral prescription of a licensed practitioner from most of the labeling and packaging requirements which ordinarily apply to drugs. To get the exemption, the container in which the prescription medicine is dispensed must bear a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in the prescription.

The exemption does not relax the prohibition against false or misleading labeling, the prohibition against selling an imitation drug, or offering a drug for sale under the name of another drug; nor does the exemption change the requirement that any drug containing insulin, penicillin, streptomycin, aureomycin, chloramphenicol, or bacitracin must be pretested and certified, or the requirement that any official drug must be packaged as required by the official compendium, or that any drug liable to deterioration must be packaged in accordance with regulations established under existing law. The exemption will not be applicable to any drug dispensed in the course of the conduct of the business of dispensing drugs pursuant to diagnosis by mail or otherwise without examination of the patient. The latter provision follows the existing law.

It is provided in paragraph (2) that the exemption provided thereby shall not apply to habit-forming, dangerous, and new drugs dispensed in violation of the prescription requirements of paragraph (1).

Paragraph (3)—Exemption from prescription requirements

This paragraph permits the Administrator by regulations to remove habit-forming and new drugs from the prescription requirement of paragraph (1) when that requirement is not necessary for the protection of the public health. These drugs are the ones covered by subparagraphs (A) and (C) of paragraph (1). This relaxation is necessary to permit the sale without prescription of drugs containing small amounts of habit-forming drugs as components, and to permit the sale of new drugs without prescription when that safeguard is unnecessary.

Paragraph (4)—Labeling of prescription drugs and over-the-counter drugs

This paragraph requires that any drug to which paragraph (1) applies must bear on its label the statement "Caution: Federal law prohibits dispensing without prescription." It also provides that a drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears any statement which represents or implies that the dispensing of the drug without the prescription of a licensed practitioner is prohibited.

Paragraph (5)—Hearings and judicial review

This paragraph deals with the procedure to be followed in a case where an interested party desires to secure a formal hearing or judicial review with respect to a determination by the Administrator as to whether a drug is a "dangerous" drug according to the standard contained in subparagraph (B) of paragraph (1). This procedure is made available to contest either a proposed determination by the Administrator, to seek a determination that a drug which has already been listed should be removed from the list, or to seek to have placed on the list a drug which is not on the list.

For any of these purposes an interested person may file a petition with the Administrator. Where the petition is for the purpose of opposing a proposed determination that a drug is "dangerous", the filing of a petition will stay the operation of paragraph (1) with respect to the drug until a petition for judicial review can be filed, and interim relief sought, under section 10 (d) of the Administrative Procedure Act. This provision, together with the procedural safeguards of the Administrative Procedure Act, will insure that the Administrator cannot place a drug on the list until interested persons have had full opportunity to test the validity of the Administrator's action.

When a petition is filed stating reasonable grounds, the Administrator will be under a duty to give public notice of the proposal made in the petition and to give all interested persons a reasonable opportunity to present their views, orally or in writing, and it will be his duty to act on the petition as soon as is practicable. Any interested person who is dissatisfied with the Administrator's action may (if he files an objection to such action, stating reasonable grounds therefor, within 30 days after it is made public) demand and secure a public hearing before the Administrator for the taking of evidence of experts who are qualified by scientific training and experience to testify on the question of whether the drug in question is safe and efficacious for use only after professional diagnosis by, or under the supervision of, a practitioner licensed by law to administer the drug. As soon as practicable after the hearing, the Administrator must issue an appropriate order. The Administrator may make his order only after consideration of the whole record and in accordance with reliable, probative, and substantial evidence, and he will be required to make detailed findings of the facts on which he based his order.

The order of the Administrator will be subject to judicial review in accordance with the provisions of section 701 (f) and (g) of the Federal Food, Drug, and Cosmetic Act. These are the judicial review provisions which are now applicable to the review of orders issued under certain other provisions of the act. Such review will be by the appropriate circuit court of appeals of the United States, and may be had upon the filing of a petition with the court at any time prior to the ninetieth day after the issuance of the order by the Administrator. Review will be upon the basis of the "substantial evidence" rule which is the generally applicable provision for judicial review contained in the Administrative Procedure Act.

Paragraph (6)—Narcotics laws unaffected

This paragraph provides that nothing in subsection (b) shall be construed to relieve any person from any requirement prescribed by or under law with respect to narcotics or marihuana.

SECTION 2. EFFECTIVE DATE

This section of the bill provides that its provisions shall take effect 6 months after the date of its enactment into law. This postponement of the effective date of the legislation is deemed to be necessary in order that the Administrator will have time to take steps, before the legislation takes effect, with a view to determining which drugs are "dangerous" under the standard prescribed in subparagraph (B) of section 503 (b) (1).

CHANGES IN EXISTING LAW

In compliance with paragraph 2a of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as introduced, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, existing law in which no change is proposed is shown in roman):

SECTION 503 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

EXEMPTIONS IN CASE OF DRUGS AND DEVICES

SEC. 503. (a) The Administrator is hereby directed to promulgate regulations exempting from any labeling or packing requirement of this Act drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

[(b) A drug dispensed on a written prescription signed by a physician, dentist, or veterinarian (except a drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail), shall if—

[(1) such physician, dentist, or veterinarian is licensed by law to administer such drug, and

[(2) such drug bears a label containing the name and place of business of the dispenser, the serial number and date of such prescription, and the name of such physician, dentist, or veterinarian,

be exempt from the requirements of section 502 (b) and (e), and (in case such prescription is marked by the writer thereof as not refillable or its refilling is prohibited by law) of section 502 (d).]

(b) A drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 502, except paragraphs (a), (i) (2) and (3), (k), and (l), and the packaging requirements of paragraphs (g) and (h), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription, or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail or otherwise without examination of the patient. If the drug is intended for use by man and—

(1) is a habit-forming drug subject to the regulations prescribed under section 502 (d);

(2) has been found by the Administrator, after investigation and opportunity for public hearing, to be unsafe or ineffective for use without the professional diagnosis or supervision of a practitioner licensed by law;

(3) if an effective application under section 505 limits it to use under the professional supervision of a practitioner licensed by law, such exemption shall apply only if such drug is dispensed upon a written prescription of a practitioner licensed by law to administer such drug or upon an oral prescription of such practitioner which is reduced to writing and filed by the pharmacist, or is dispensed by refilling a prescription if such refilling is authorized by the prescriber in the original prescription or by oral order and such order is reduced to writing and filed by the pharmacist.

The Administrator may by regulation remove drugs subject to section 502 (d) and section 505 from the provision of this subsection when such requirements are not necessary for the protection of the public health.

A drug which is subject to clause (1), (2), or (3) of this subsection shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement "Caution: Federal law prohibits sale or dispensing without prescription".

The act of dispensing a drug contrary to the provisions of this subsection shall be deemed to be an act which results in the drug's being misbranded while held for sale.

Any interested person may file with the Administrator a petition proposing the addition to, or deletion from, the list of drugs promulgated by the Administrator in accordance with clause (2) hereof. Such petition shall set forth the proposal in general terms and shall state reasonable grounds therefor. The Administrator shall give public notice of the proposal and an opportunity for all interested persons to present their views thereon, orally or in writing, and as soon as practicable thereafter shall make public his action upon such proposal. At any time prior to the thirtieth day after such action is made public any interested person may file objections to such action, specifying with particularity the changes desired, stating reasonable grounds therefor and requesting a public hearing upon such objections. The Administrator shall thereupon, after due notice, hold such public hearing. As soon as practicable after completion of the hearing, the Administrator shall by order make public his action on such objections.

An order so issued by the Administrator may, within ninety days after its issuance, be appealed by any interested person in accordance with the provisions prescribed in section 701 (f) and (g) of this Act, except that an appeal from the Administrator's order issued hereunder shall be in the nature of a trial de novo, without presumptions in favor of either party to such appeal.

The provisions of this section of the Act shall not be applicable to drugs now included or which may hereafter be included within the classifications stated in section 3220 of the Internal Revenue Code (26 U. S. C. 3220), or to marijuana as defined in section 3238 (b) of the Internal Revenue Code (26 U. S. C. 328 (b)).

APPENDIX

FEDERAL SECURITY AGENCY,
Washington, April 30, 1951.

Hon. ROBERT CROSSER,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington 25, D. C.

DEAR MR. CHAIRMAN: This letter is in response to your request of March 21, 1951, for a report on H. R. 3298, a bill to amend section 503 (b) of the Federal Food, Drug, and Cosmetic Act.

This bill is in substantially the same form as that introduced as H. R. 8904 in the Eighty-first Congress, second session, which this Agency endorsed. Section 503 (b) of the present law recognizes only written prescriptions, whereas the section as amended by the bill would recognize oral prescriptions as well, with the safeguard under certain circumstances that the pharmacist reduce the oral order to writing and file it. The present law does not provide a clear differentiation between those drugs which should be dispensed solely on prescription and those which may be sold over the counter. It is the intent of the bill to supply this deficiency by requiring the dispensing on prescription only of specified habit-forming drugs and those specifically designated in regulations or new drug applications which cannot be safely and effectively used without professional diagnosis and supervision. The bill provides that the labels of such drugs bear a caution against dispensing without prescription.

This Agency is sympathetic to the purposes of the bill. It would clarify the obligations of pharmacists, would promote the operations of all on the high standards now followed by the majority, and would afford better protection to the public health than the present law against abuses by a minority in dispensing highly potent drugs by over-the-counter sales or by refilling prescriptions without the knowledge and approval of the prescriber.

The bill contains, however, three new paragraphs beginning at line 15 of page 3 and continuing to line 14 of page 4. The most significant feature of the new paragraphs is a "trial de novo" (lines 12–14 on p. 4) in a United States court of appeals on appeals from the Administrator's orders. An outline of the procedure leading up to the proposed "trial de novo" is relevant. Clause (2) of new section 503 (b) requires that an opportunity for public hearing be afforded before the Administrator promulgates a list of drugs that are unsafe or ineffective for use without professional diagnosis and supervision and thus must therefore be dispensed only on prescription. This public hearing, it would seem, may be held under the informal rule-making procedure of section 4 of the Administrative Procedure Act. No appeal would lie at this stage from the resulting action of the Administrator (see Administrative Procedure Act, sec. 10).

The last paragraph on page 3 of the bill provides for a formal hearing and judicial review when any interested party disagrees with the order of the Administrator issued under clause 2. The procedural steps provided are as follows: (1) Any interested person may file a petition setting forth the proposal for addition to or deletion from the list of drugs, with a statement of reasonable grounds. (2) Public notice of the proposal and an opportunity to present views by interested parties are given. (3) A decision of the Administrator with respect to that proposal is made. (4) Objections to the decision may be filed within 30 days, with a request for a public hearing on such objections. (5) A hearing on the objections is held. The formal hearing provisions of sections 7 and 8 of the Administrative Procedure Act would apparently apply to that hearing. (6) An order is issued. This order is subject to judicial review in accordance with section 701 (f) and (g) of the Food and Drug Act, except that such review shall be "in the nature of a trial de novo, without presumptions in favor of either party to such appeal."

These provisions are in general patterned after section 507 (f) (21 U. S. C. 357 (f)) relating to the certification of antibiotic drugs. The Administrator's order with respect to objections filed by interested parties concerning his regulations under section 507 (f) is subject to the provisions of section 701 (f) and (g) (21 U. S. C. 371 (f) and (g)). Section 701 (f) provides that the findings of the Administrator as to the facts, if supported by substantial evidence, shall be conclusive. But the bill expands the scope of review. The bill directs that the "appeal" is to be in the nature of a "trial de novo" without presumptions in favor of either party to such appeal. The concept of a "trial de novo" at the appellate level departs radically from legislation governing the review of rules and regulations issued by administrative agencies, and goes beyond the require-

ments of the Administrative Procedure Act which was intended to bring uniformity to administrative proceedings and their judicial review. The scope of judicial review now embodied in section 10 (e) of the Administrative Procedure Act is that agency action shall be upheld where it is supported by "substantial evidence," but the court is directed to review the whole record in determining whether the evidence is substantial. This provision has recently been examined by the Supreme Court in *Universal Camera Corp.* v. *National Labor Relations Board*, decided February 26, 1951. The specific provision to this effect in section 701 (f) of the Federal Food, Drug, and Cosmetic Act, and its conformity to the Administrative Procedure Act, was judicially approved in *Willapoint Oysters* v. *Ewing* (174 F. 2d 676, cert. den. 338 U. S. 860).

The proposed bill, in contrast, would extend the function of the reviewing court beyond that contemplated by the Administrative Procedure Act. The appellate court in a "trial de novo" would become a trier of facts with respect to difficult questions of drug action, questions which are not at all suited for judicial determination but which require expert scientific knowledge for informed judgment. The determination of such a question is peculiarly within the expert competence of an administrative agency yet the court would be expressly enjoined to attach no "presumptions" to its action, i. e., to give no weight to it. The Administrative Procedure Act has recognized the principle of deference to administrative expertise by providing for review as to the legal sufficiency of the evidence presented in support of a regulation, not a complete and needless retrial of the facts in an appellate court.[1]

There is serious question, moreover, as to the propriety of conferring the power to make a determination that is essentially legislative upon a "constitutional court." This was declared objectionable by the Supreme Court in *Federal Radio Commission* v. *General Electric Co.* (281 U. S. 464 (1930)) and in the cases there cited. In the General Electric case, the Radio Act of 1927 had authorized the court of appeals, after decision by the Commission, to take additional evidence, hear, review, and determine the appeal upon the record and the evidence, and alter or revise the decision appealed from—in short, a review de novo. While the opinion acknowledged that Congress may make the Court of Appeals for the District of Columbia a "superior and revising" agency, it concluded that the Supreme Court could not be invested with similar powers. In this connection, it should be noted that section 701 (f) (4) of the Food and Drug Act, which is incorporated in the bill by reference, would confer jurisdiction on the Supreme Court to review decisions of the courts of appeals. Moreover, under the bill proceedings for judicial review could be filed in the court of appeals for the circuit in which the petitioner resides or has his principal place of business, which, in most cases, would be outside the District of Columbia. Such other courts of appeals, being "constitutional courts," would be subject to the same disability in this respect as the Supreme Court.

The legislative history of the present act reveals that Congress was confronted with a similar problem as to the scope of review of administrative regulations and rejected the solution now proposed. As reported out with an amendment by the House Committee on Interstate and Foreign Commerce after passage by the Senate, S. 5, Seventy-fifth Congress, contained a special review provision in section 701 (f) permitting anyone appealing from a regulation to adduce additional evidence before a district court, and further providing that the court might take such further action as "justice may require" (H. Rept. No. 2139, 75th Cong., 3d sess., pp. 11–12). The Supreme Court, in *Federal Security Administrator* v. *Quaker Oats Co.* (318 U. S. 218 (1943)) explained the elimination of this provision: "* * * before enactment, the conference committee substituted for these provisions those which became section 701 (f) of the act. While under that section the Administrator's regulations must be supported by findings based upon 'substantial evidence' adduced at the hearing, the Administrator's findings as to the facts if based on substantial evidence are conclusive. In explaining these changes the chairman of the House conferees stated on the floor of the House that 'there is no purpose that the court shall exercise the functions that belong to the executive or the legislative branches' (83 Congressional Record, p. 9096)."

The conference committee further noted, with respect to the review provided in section 701 (f) (S. Rept. No. 2716, 75th Cong., 3d sess.):

"The type of judicial review provided in the agreement is as broad as the Constitution permits in the case of review by a constitutional court. It is to be noted that the function of the Secretary in making regulations and orders to

[1] In any event, the use of the word "trial" in the bill is in itself a misnomer. In all probability the drafters intended to have a review on the record and not a trial de novo.

carry them out is legislative in character * * *. Judicial review of the Secretary's action to determine if there was substantial evidence to support the finding, and of course, upon constitutional questions, may be had."

To permit a review by trial de novo at the level of the court of appeals would not only impede and hamper the enforcement program with respect to the most dangerous drugs, but would burden these courts with a legislative function which, it appears likely, they may not constitutionally be called upon to perform.

This bill also authorizes oral prescriptions which are reduced to writing and filed by the pharmacist. It does not require that the physician confirm or agree to confirm the prescription in writing. In this, it departs from the bill which we previously endorsed. We believe that at the very least the physician should agree to confirm his oral prescriptions in writing within 72 hours, and that he should not be entirely freed from his responsibility to confirm because the pharmacist reduced the telephone order to writing.

We therefore recommend that the bill, with the above-suggested amendment, with the deletion of the excepting provision in lines 12–14 on page 4, and with certain clarifications and technical amendments which we should like to suggest at the appropriate time, be enacted by the Congress.

The Bureau of the Budget advises that there is no objection to the submission of this report to your committee.

Sincerely yours,

OSCAR R. EWING, *Administrator.*

APRIL 30, 1951.

Hon. ROBERT CROSSER,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D. C.

MY DEAR MR. CHAIRMAN: This is in response to your request for the views of the Department of Justice concerning the bill (H. R. 3298) to amend section 503 (b) of the Federal Food, Drug, and Cosmetic Act.

Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. 352) sets forth the various circumstances under which drugs and devices will be deemed to be misbranded. Section 503 (b) (21 U. S. C. 353 (b)) specifies certain exemptions with respect to drugs dispensed on written prescriptions.

The bill would amend section 503 (b) so as to provide that a drug dispensed by filling or refilling a written or oral prescription shall be exempt from the requirements of section 502, except with respect to certain packaging requirements and those provisions of the section which provide that a drug shall be deemed to be misbranded if its labeling is false or misleading in any particular or if it is an imitation of another drug or if it is offered for sale under the name of another drug, and except with respect to the provisions of the act dealing with insulin and the various antibiotics covered by the statute. The measure provides, however, that such exemption shall prevail only if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in the prescription.

Separate provision is made if the drug is intended for use by man, and is (1) a habit-forming drug subject to the regulations prescribed under section 502 (d) (21 U. S. C. 352 (d)), or (2) has been found by the Federal Security Administrator to be unsafe or ineffective for use without the professional diagnosis or supervision of a practitioner licensed by law, or (3) if an effective new drug application under section 505 (21 U. S. C. 355) limits it to use under the professional supervision of a licensed practitioner. In such event the exemption is to apply only if the drug is dispensed upon a written prescription or upon an oral prescription which is reduced to writing and filed by the pharmacist, or is dispensed by refilling a prescription if such refilling is authorized by the prescriber in the original prescription or the oral order and such order is reduced to writing and filed by the pharmacist. A drug which falls within the three categories mentioned immediately above will be misbranded if at any time prior to its being dispensed its label fails to bear the statement "Caution: Federal law prohibits sale or dispensing without prescription."

The bill also provides that the act of dispensing the drug contrary to the provisions of the bill shall be deemed to be an act which results in the drug's being misbranded while held for sale. This would insert into the Federal Food, Drug, and Cosmetic Act the theory, based on regulations, pursuant to which the Food and Drug Administration has recommended prosecution of druggists who sell,

without prescriptions, drugs bearing the so-called prescription legend and which have not been removed from the immediate containers in which they were shipped in interstate commerce. Such a sale by a druggist would be in violation of section 301 (k) (21 U. S. C. 331 (k)).

The bill also provides a procedure whereby any interested person may file a petition with the Federal Security Administrator proposing the addition to or deletion from the list of drugs found to be unsafe or ineffective for use in accordance with clause (2) of section 503 (b). Upon the filing of such a petition, the Administrator is required to give public notice of the proposal and a hearing thereon, and as soon as practicable thereafter shall make public his action upon such proposal. Any interested person may file objections to such action and request a public hearing upon such objections. The Administrator shall thereupon after due notice hold such public hearing and as soon as practicable thereafter by order make public his action on such objections. The order of the Administrator may within 90 days after its issuance be appealed to the court of appeals in accordance with the provisions prescribed in section 701 (f) and (g) of the Act (21 U. S. C. 371 (f) and (g)), except that such appeal shall be in the nature of a trial de novo without presumptions in favor of either party to such appeal.

The bill also provides that its provisions shall not apply to drugs now included or which may hereafter be included within the classification stated in section 3220 of the Internal Revenue Code or to marijuana as defined in section 3238 (b) thereof.

Whether the bill should be enacted involves a question of policy concerning which this Department prefers not to make any recommendation. There are certain features of the measure, however, concerning which the committee may wish to give further consideration.

The bill provides for two public hearings in connection with a proposal for the addition to or deletion from the list of drugs found to be unsafe in accordance with the provisions of clause 2. A public hearing is provided for on the original proposal, and again provided for in connection with objections to the action of the Administrator upon the proposal. It would seem that the one public hearing on the original proposal would be sufficient.

The bill also provides for an appeal from the order of the Administrator. It is assumed that the order referred to is that made after the public hearing on the objections to the previous action of the Administrator. The review proceeding is to be in accordance with the provisions of section 701 (f) and (g) of the act, except that the appeal shall be in the nature of a trial de novo. It will be noted, however, that the review proceedings in section 701 are confined to questions of law. The court is given jurisdiction to affirm the order complained of or to set it aside in whole or in part. If the order refuses to issue, amend, or repeal a regulation and such order is not in accordance with law, the court shall by its judgment order the Administrator to take action with respect to the matter, in accordance with law. In a de novo proceeding the court ordinarily has the power and function to make its own findings and judgment. Such a trial contemplates not only the record before the Administrator but the testimony of additional witnesses if desired. No such procedure is contemplated under section 701. The provision for a trial de novo would be incompatible with the review procedure provided for and leaves an ambiguity and doubt as to what the function of the appellate court would be. In addition, such a proceeding would appear to make the appellate court a revising agency and its action in the nature of an administrative decision. A question arises as to whether such a function is within the judicial power conferred upon Federal courts by the Constitution. Compare *Radio Commission* v. *General Electric Co.* (281 U. S. 464).

It might be desirable to consider the question of review in connection with the action of the Administrator in designating unsafe drugs under clause (2). It is believed that a review from such a determination in accordance with the procedure in section 701, would fully protect the rights of any person adversely affected since the Supreme Court has recently held that in considering the question of whether an order of this nature is supported by substantial evidence, the appellate court shall review the whole record.

The Director of the Bureau of the Budget has advised that there is no objection to the submission of this report.

Yours sincerely,

PEYTON FORD,
Deputy Attorney General.

ADMINISTRATIVE OFFICE OF THE UNITED STATES COURTS,
Washington 13, D. C., March 29, 1951.

Hon. ROBERT CROSSER,
House Office Building, Washington, D. C.

DEAR CONGRESSMAN CROSSER: I have compared the bill about which you have written me on March 22, 1951, to amend section 503 (b) of the Federal Food, Drug, and Cosmetic Act (H. R. 3298) with the present provision of the statute. The statute deals with the exemption from the requirements of the Federal Food, Drug, and Cosmetic Act in relation to the labeling of drugs handled in interstate commerce of drugs that are dispensed on a written prescription of a licensed physician, dentist, or veterinarian. The bill would make more detailed and specific the safeguards against abuse of the exemption from the provisions of the general statute.

The only feature of the bill that my office may qualify me to discuss is the provision in the next to the last paragraph of subsection (b) of section 503 of the statute as proposed to be amended (p. 4, lines 8 to 14) and especially the last clause on lines 11 to 14 of the printed bill. This section provides for appeals from orders of the Federal Security Administrator adding to or deleting from the list of drugs promulgated by him as "unsafe or ineffective for use without the professional diagnosis or supervision of a practitioner licensed by law" (clause 2, p. 2, lines 12 to 16 of the printed bill). It defines the procedure on appeal in general by reference to section 701 (f) (g) of the statute (21 U. S. C. 371 (f) (g)). These subsections provide that appeals from the orders of the Administrator may be filed in the United States court of appeals for the circuit in which the person taking the appeal resides or has his principal place of business. The pending bill would not change the court which would have jurisdiction to review orders of the Administrator in reference to the subject matter affected. That court would continue to be the court of appeals for the circuit.

The exception at the end of the paragraph would, however, make an important change from the present statute in respect of the procedure on review. Sections 701 (f) (g) of the present statute (21 U. S. C. 371 (f) (g)) prescribe that when a review is taken the review shall be had upon a transcript of the record and proceedings before the Administrator. "The findings of the Administrator as to the facts, if supported by substantial evidence, shall be conclusive." The paragraph referred to of the pending bill would change the practice and make the appeal "in the nature of a trial de novo, without presumptions in favor of either party to such appeal."

The Judicial Conference of the United States under which I act has not considered the particular bill and, therefore, I am not in a position to express an official opinion in regard to it, although the conference is on record in opposition to the procedure of a trial de novo by a three-judge court for review of the orders of administrative agencies. I would point out that the provision that appeals from the order of the Administrator shall be in the nature of a trial de novo, reverses what has been for 20 years or more a uniform trend in the Federal Government to provide for the hearing and decision of appeals from orders of administrative agencies by the courts of appeals upon the record made before the agencies. This procedure has been repeatedly provided for by the Congress, most recently by a law passed at the end of the Eighty-first Congress and approved December 29, 1950, in relation to the review of certain orders of the Federal Communications Commission, the Secretary of Agriculture, and the United States Maritime Commission (Public Law 901 of the 81st Cong.). That law originated in a recommendation of such legislation by the Judicial Conference.

The considerations underlying the act are stated in House Report No. 2122 of the Eighty-first Congress. The report states that review by the court of appeals of orders of administrative agencies upon the record made before the agencies "has important advantages in simplicity and expedition" over a trial de novo by a three-judge court. From the report I quote pertinent portions as follows:

"First, the submission of the cases upon the records made before the administrative agencies will avoid the making of two records, one before the agency and one before the court, and thus going over the same ground twice * * *."

"Second, in many cases in which hearing in the district courts by panels of three judges is now required there will be a large saving of judicial time and energy. It is generally recognized that three-judge courts are not well adapted for conducting hearings. The necessity of holding conferences whenever questions arise in the course of the proceedings, as they repeatedly do in relation to such matters as the admissibility of evidence, very much slows the trial. In addition the proceeding takes the time of three judges, whereas one would be sufficient at this

preliminary stage of the case. The method of review prescribed by the proposed bill would secure the collaboration of three judges at the stage where it is useful, namely, in the decision without consuming their time unnecessarily in the preceding phases of the case."

While the practice which was changed by Public Law 901 of the Eighty-first Congress in reference to the agencies there concerned was trial de novo by a three-judge district court and the trial de novo on appeal from orders of the Administrator in the field of the pending bill would be such a trial by three judges of a court of appeals, all the disadvantages of trial de novo by a three-judge court referred to in the report of the last Congress would apply. There would be the same going over the ground twice in two records, the same difficulty inevitable in a court of three judges in conferring upon questions of the admission of evidence and other interlocutory matters arising during the proceedings, thus slowing the trial, and the same absorption of the time of three judges where one would be sufficient. It may be added that in no case at present, with perhaps an occasional extraordinary exception does a court of appeals sit as a trial court or hear evidence. The present statute which the pending bill would change, provides that even in those instances in which the court allows the petitioner to adduce additional evidence, such evidence shall be taken before the Administrator and adduced to the court rather than taken by the court of appeals directly.

The precedent which would be set by the pending bill of having the hearing on review conducted by the court of appeals as a trial de novo would be a radical departure. It would be contrary to the general judgment in reference to the effective procedure for the review of orders of administrative agencies as expressed in the report and law of the last Congress which have been cited. Such a change of method at this time when there is serious congestion in a number of Federal courts would tend to increase the present difficulties and delays in the handling of the judicial business.

Sincerely yours,

HENRY P. CHANDLER.

ADMINISTRATIVE OFFICE OF THE UNITED STATES COURTS,
Washington 13, D. C., April 12, 1951.

Hon. ROBERT CROSSER,
House Office Building, Washington, D. C.

DEAR CONGRESSMAN CROSSER: In further reference to the bill to amend section 503 (b) of the Federal Food, Drug, and Cosmetic Act (H. R. 3298) about which you inquired of me on March 22, 1951, I would point out that the provision for judicial review of actions of the Administrator contained in the next to the last paragraph of subsection (b) of section 503 of the statute as proposed to be amended (p. 4, lines 11 to 14 of the bill) is in conflict with the criterion prescribed in such long-considered and deliberate enactments of the Congress as the Administrative Procedure Act approved June 11 1946 (60 Stat. 237), and the Labor Management Relations Act, 1947, commonly known as the Taft-Hartley Act approved June 23, 1947 (61 Stat. 136). The legislative policy in reference to the weight to be given to the decisions of administrative agencies by the courts and the evidence necessary to sustain them were recently considered at length by the Supreme Court of the United States and reviewed in detail in the case of *Universal Camera Corporation* v. *National Labor Relations Board* (No. 40 at the present term of the court). At the same time the court rendered a brief corollary opinion applying the same standard of review in the case of *National Labor Relations Board* v. *Pittsburgh Steamship Co.* (No. 42 at the present term of court). Briefly, the development of the standard to be applied by the courts on the review of orders of administrative agencies as set forth in the opinion in the case of the Universal Camera Corp., supra, is this:

The original National Labor Relations Act, commonly known as the Wagner Act, provided in section 10 (e) in reference to the judicial review of decisions of the National Labor Relations Board that "The findings of the Board as to the facts, if supported by evidence, shall be conclusive" (49 Stat. 449, 454, 29 U. S. C. 160 (e)).

The Supreme Court in *Washington, V. & M. Coach Co.* v. *Labor Board* (301 U. S. 142) construed "evidence" to mean substantial evidence. In the early years of application of the Wagner Act the opinion became current that on judicial review of an order of the National Labor Relations Board, if there was in the record made before the Board evidence which taken by itself would justify the Board's decision, that would be enough to satisfy the test of substantial evidence irrespec-

tive of other parts of the record. The Supreme Court in its opinion supra stated that there were expressions in some of the opinions of that Court which were cited (*Labor Board* v. *Waterman Steamship Corp.*, 309 U. S. 206; *Labor Board* v. *Bradford Dyeing Assn.*, 310 U. S. 318; and *Labor Board* v. *Nevada Consolidated Copper Corp.*, 316 U. S. 105) that whether or not so contemplated gave color to that view.

The doctrine stated brought criticism which was reflected in the passage in 1940 of the Walter-Logan bill. Even so, the bill adopted the test for judicial review of orders of administrative agencies which was expressed in the Wagner Act as construed by the Supreme Court, that the findings of fact by an agency could be set aside by a court if "not supported by substantial evidence." President Roosevelt vetoed the bill partly because it limited too strictly the administrative process and partly because an experienced committee appointed by the Attorney General of the United States was then engaged in a study of the actual operation of the administrative process. That committee submitted its final report in 1941. The majority report observed that there was dissatisfaction with the fact-finding procedures then being used by administrative bodies but concluded that it would be inadvisable to depart from the test on judicial review of substantial evidence which then applied to the review of orders of administrative agencies. Three members of the committee, however registered dissent on the ground that the recommendations of the committee did not go far enough to correct defects in the procedures of administrative agencies. Among other things, the dissenting members of the committee recommended as one principle of judicial review applicable generally to administrative agencies, that review should extend to "findings, inferences, or conclusions of fact unsupported, upon the whole record, by substantial evidence." The Supreme Court in the Camera Corp. case supra states that reference to the whole record appears for the first time in the recommendation of the minority of the Attorney General's committee. The opinion of the Court goes on to state that this idea found its way into the Administrative Procedure Act enacted in 1946 (pp. 6 to 8 of the opinion in the Camera Corp. case supra). So the Administrative Procedure Act in section 10 (e) provided that on judicial review the court should hold unlawful and set aside agency action if—

"(5) unsupported by substantial evidence in any case subject to the requirements of sections 7 and 8 or otherwise reviewed on the record of an agency hearing provided by statute; or (6) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court. In making the foregoing determinations the court shall review the whole record or such portions thereof as may be cited by any party, and due account shall be taken of the rule of prejudicial error" (60 Stat. 244, 5 U. S. C. 1009 (e)).

It is important to note that the statute requires that a court in determining whether or not an order of an administrative agency under review is "unsupported by substantial evidence" shall "review the whole record or such portions thereof as may be cited by any party." In short, in adopting the Administrative Procedure Act the Congress did not do away with the presumption on review in favor of the decision of an administrative agency if supported by substantial evidence, but made it unmistakably clear that the reviewing court in determining whether there was substantial evidence to justify the conclusion must take into account the whole record, or any portions cited by any parties, which doubtless would be all the pertinent parts.

The Supreme Court in its recent opinion in the Camera Corp. case points out that the amendment of the Wagner Act by the Taft-Hartley Act adopted in effect the same standard for judicial review of decisions of the National Labor Relations Board, that was prescribed for administrative agencies generally by the Administrative Procedure Act. The provision of the Taft-Hartley law appears in section 10 (e) that the findings of the National Labor Relations Board "with respect to questions of fact if supported by substantial evidence on the record considered as a whole shall be conclusive" (29 U. S. C., 1946 ed., Supp. III, 160 (e)).

The Supreme Court points out in the Camera Corp. case that the effect of the Administrative Procedure Act and the Labor-Management Relations Act, 1947, has been to require reviewing courts to carry the scrutiny of decisions of administrative agencies further than was thought in some legal circles to be necessary prior to the passage of the Administrative Procedure Act. Upon this the Court said:

"Whether or not it was ever permissible for courts to determine the substantiality of evidence supporting a Labor Board decision merely on the basis of evidence which in and of itself justified it, without taking into account contra-

dictory evidence or evidence from which conflicting inferences could be drawn, the new legislation definitively precludes such a theory of review and bars its practice. The substantiality of evidence must take into account whatever in the record fairly detracts from its weight. This is the clear meaning of the reference in both statutes to 'the whole record.' Committee reports and the adoption in the Administrative Procedure Act of the minority views of the Attorney General's Committee demonstrate that to enjoin such a duty on the reviewing court was one of the important purposes of the movement which eventuated in that enactment."

The Supreme Court is careful to point out in its recent decision that it does not mean that in reviewing the decision of an administrative agency a court shall consider the record before the agency de novo and substitute its judgment for that of the agency. The court expressed its meaning upon the necessity of considering "the whole record" as follows:

"To be sure, the requirement for canvassing 'the whole record' in order to ascertain substantiality does not furnish a calculus of value by which a reviewing court can assess the evidence. Nor was it intended to negative the function of the Labor Board as one of those agencies presumably equipped or informed by experience to deal with a specialized field of knowledge, whose findings within that field carry the authority of an expertness which courts do not possess and therefore must respect. Nor does it mean that even as to matters not requiring expertise a court may displace the Board's choice between two fairly conflicting views, even though the court would justifiably have made a different choice had the matter been before it de novo. Congress has merely made it clear that a reviewing court is not barred from setting aside a Board decision when it cannot conscientiously find that the evidence supporting that decision is substantial, when viewed in the light that the record in its entirety furnishes, including the body of evidence opposed to the Board's view."

The provision of the pending bill that the review before a court of appeals of a decision of the Administrator under the Federal Food, Drug, and Cosmetic Act "shall be in the nature of a trial de novo, without presumptions in favor of either party" is plainly contrary to the policy of the Congress deliberately adopted in the Administrative Procedure Act after years of discussion and consideration and followed in the Taft-Hartley law. That policy is that the judical review of orders of administrative agencies shall be upon the record made before the agencies and not in the nature of a second trial, and that if the action of the agency is supported by substantial evidence when considered in the light of the entire record, it shall stand. It would seem that the Congress might hesitate to change a policy based upon experience and finally crystallized in outstanding legislative acts, as the pending bill would do.

Sincerely yours,

HENRY P. CHANDLER.

MINORITY REPORT

We do not have any objections to the provisions of the bill which give authority for the filling and refilling of oral or telephone prescriptions. The present law does not recognize oral prescriptions, and we agree with the majority that, for the benefit of the public, the physician, and the retail druggist, the filling and refilling of oral prescriptions, under proper safeguard should be permitted. We also approve restricting the refilling of prescriptions dispensing dangerous drugs, except when authorized orally or in writing by the physician. We believe that the enactment of the foregoing provisions of the bill is as far as Congress should go at this time in making changes in the present law with respect to the labeling and dispensing of drugs. The remaining provisions would make basic changes in the method of determining which drugs are dangerous and may be sold only on prescription, and which drugs are safe and may be sold over the counter. We think the present method, which leaves this determination to the courts, should be left unchanged except that a proper standard to be applied in determining whether a drug is dangerous should be incorporated in the statute.

BASIS FOR OBJECTIONS

The most objectionable feature of the bill lies in the provision which would give the Federal Security Administrator the power to determine the category in which a drug should be placed. In other words, the Administrator would decide by the issuance of regulations the drugs which could be sold only upon prescription and, by the process of exclusion, those which could be sold over the counter without prescription. This we believe to be a dangerous delegation of authority to the Federal Security Administrator and one that is wholly unnecessary. Moreover, instead of solving the problems of the public, the retail druggist and the physician, it will add to present difficulties by increased bureaucratic regulation.

Admittedly, there is some degree of confusion today arising from labeling policies by drug manufacturers. In some instances one company will label a drug for prescription sale only, while another will label the same drug for over-the-counter use. But there is a remedy for this situation under existing law. If a drug manufacturer places a dangerous drug on the market without a proper caution label against nonprescription use, he may be prosecuted criminally, and the Government may seize his product. Similarly, if a drug manufacturer labels a harmless drug for prescription use only he may likewise be proceeded against for erroneous labeling. If a druggist dispenses a drug which the manufacturer has not properly labeled he is not subject to prosecution while acting in good faith.

Retail druggists have been told that if this bill passes they could then rely upon the label of the manufacturer and safely dispense all

drugs in accordance therewith. But such is far from being the case. Under the amended bill the druggist could not safely dispense any drug without referring to the regulations of the Federal Security Administrator. If he sold a drug contrary to the regulations of the Administrator he would be subject to prosecution and the defense of good faith would not be available to him.

THE DRUGGISTS' DILEMMA

It is reliably estimated that if this bill became a law on its effective date approximately 30,000 drugs would be subject to regulation. This would mean that every druggist in the country would have to obtain copies of the Security Administrator's regulations from the Federal Register, and go over his entire inventory and relabel his drugs in conformity with such regulations. This initial task would be a tremendous burden to the average druggist, but his troubles wouldn't end there. Thenceforth, he would have to review the regulations in the Federal Register from day to day and week to week in order to be sure that he was complying with the Administrator's list.

We are all familiar with the problems that beset the small-business man today because of OPS and other bureaucratic regulation. For Congress to impose the additional regimentation upon the already harried and frustrated small-business man is not only unreasonable but ridiculous.

We maintain, therefore, that the present system of determining prescription drugs by judicial process on a case-by-case basis is much to be preferred over the suggested remedy, which would create more headaches than it would solve. We have been constrained to disagree with the majority and to file this report because we are convinced that the bill as reported constitutes an excessive and entirely unwarranted grant of discretionary power to the Federal Security Administrator.

REGULATION OF THE DRUG INDUSTRY

The exemption of prescription refills and of oral prescriptions from certain labeling requirements of the Federal Food, Drug, and Cosmetic Act has been availed of for the advancement of a plan to regulate the drug industry. The bill as reported empowers the Administrator to restrict to prescription sale all articles included within the broad definition of the word "drug" which he has determined to be "safe and efficacious for use only after professional diagnosis by, or under the supervision of, a practitioner licensed by law to administer such drug."

The word "drug" as defined in the Federal Food, Drug, and Cosmetic Act, means: (1) articles recognized in the United States Pharmacopoeia, the Homeopathic Pharmacopoeia of the United States, and the National Formulary; (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any of the foregoing articles.

This definition includes substances, compounds, mixtures, and fabrications of all kinds and forms used, or intended to be used, for the purposes above stated. There was testimony at the hearings that there are approximately 30,000 such "drugs." Any such drug intended for use by man which "on the basis of opinions generally held among experts qualified by scientific training and experience to evaluated the safety and efficacy of such drug" the Administrator determines "to be safe and efficacious for use only after professional diagnosis by, or under the supervision of, a practitioner licensed by law to administer such drug," shall be thereby restricted to sale only on prescription.

The bill grants the Administrator authority to separate all drugs into two classes—prescription and over the counter. Notwithstanding the majority report's references to "dangerous" and "potent" drugs, this power is not confined to them. There is little, if any, uncertainty about them. This power will find its greatest exercise in the wide field of conflicting opinion. There, as the testimony shows, "there are literally thousands of different drug items." This large field was described by the Administrator, in his testimony before the committee, as the "twilight zone." The power to govern it administratively would in time, amount to an over-all control of the manufacture, distribution, and administration of drugs. And, in the exercise of it, the Administrator would have greatly to do not only with the manufacture and distribution of drugs, but with the practice of pharmacy and medicine.

EFFICACY OF DRUGS

This control is widened by the use of the words "efficacy" and "efficacious". The majority report labors a distinction between the Administrator having the power "to determine which drugs are 'efficacious' or 'effective'" and his having the power to determine whether they "can be used efficaciously without professional diagnosis or supervision." The undersigned do not find the distinction to be as clear and as easily discernible as the majority professes. Stated either way, the power granted to the Administrator is vast in scope, and, in administrative application and interpretation, would in time become larger and embrace both statements of the authority.

The majority illustrates with the drug quinidine sulfate. More illustrative, however, is a statement in the Administrator's testimony. Asked whether there is any possibility under the bill that a prescription would be required for a refill of aspirin, the Administrator stated:

> Well, as of today, I would say "No," but I think you have to recognize that under this bill you might have an Administrator who would call a hearing to put aspirin on the list of dangerous drugs. If he held that aspirin was a dangerous drug and that was appealed to the circuit court of appeals and they upheld it, then you would be in that situation.

For further illustration, attention may be drawn to the word "diagnosis." Drugs which the Administrator determines are not safe or efficacious until "after professional diagnosis" are to be restricted to prescription sale. It is well known that there are some "experts" who entertain the view that hardly any drug is either "safe" or "efficacious" without professional diagnosis; that the layman is not competent to diagnose his ailments; and that, without being able to diagnose, he is all the more unable to prescribe for himself.

SOCIALIZED MEDICINE

In the opinion of the undersigned, there is no doubt that the bill as reported jeopardizes the traditional right of self-medication and choice of remedies. Self-medication is not confined to so-called "patent medicines." It embraces use by the public of medicaments or "drugs" which are sold over the counter and which may be purchased without prescription, whether or not they are advertised direct to the public by newspaper, magazine, and radio. The Federal Food, Drug, and Cosmetic Act, as enacted in 1938, recognized the right of self-medication, and one of the committee reports stated that it was not the purpose of the act to restrict self-medication, but to make it safe.

Thousands of articles of a medicinal or remedial nature are now lawfully available to the people and may be purchased without the expense of prescriptions—fees to doctors and prescription prices at the drug store. The undersigned believe that the bill as reported will increasingly over the years restrict the number and nature of drugs available to the public on over-the-counter sale, and thus will gradually and substantially increase the cost of medication. This bill, therefore, could very well become a handmaiden of socialized medicine in that as the costs of medical care are increased there will be a corresponding demand by the people for governmental relief.

CONTROL BY LICENSE

No grant of administrative power as wide in scope and as far-reaching in effect and implication as that in this bill has heretofore been proposed for the regulation of the drug industry. The grant of power in this bill is such as to transform, as to drugs, the Federal Food, Drug, and Cosmetic Act from a control by statutorily defined requirements to a control by license.

This proposed control is subject only to limited, uncertain, and impracticable restraint. It is no restraint to say, as the bill does, that the Administrator is to make his determination "on the basis of opinions generally held among experts qualified by scientific training and experience to evaluate the safety and efficacy" of drugs. Rather, it is lax to permit administrative authority to be constituted and rights of citizens determined on "opinions generally held" by persons unnamed in and unknown to the statute, to be selected and qualified at later times by the Administrator himself.

Practically, this bill shifts the burden of proof from the Administrator, who would assert the authority, to the citizen, who challenges it. The bill provides that the Administrator makes his determination merely on the basis of opinions of experts. If the producer or distributor of one of the drugs whose sale is restricted challenges the Administrator's determination, the bill provides that he "may file with the Administrator a petition proposing * * * a modification of a determination made or proposed to be made by the Administrator * * *." Then a sequence of time-consuming and expensive steps are begun:

(1) The Administrator gives public notice of the proposal contained in the petition and gives to "interested" persons an opportunity to present views orally or in writing;

(2) Thereafter, the Administrator makes public his action on the proposal;

(3) Within 30 days after he makes such action public, any "interested" person may file with the Administrator objections to such action, stating changes proposed, grounds therefor, and requesting a public hearing "for the taking of evidence of experts who are qualified by scientific training and experience to testify on the question of whether the drug in question is safe and efficacious for use only after professional diagnosis by, or under the supervision of, a practitioner licensed by law to administer such drug";

(4) The Administrator shall then give notice and hold a public hearing;

(5) Thereafter, the Administrator shall make his determination and issue an order;

(6) The order shall then be subject to "judicial review in accordance with the provisions of section 701 (f) and (g)" of the Federal Food, Drug, and Cosmetic Act, which are (in part):

> (f) A summons and petition served upon the Administrator, whereupon the Administrator must certify and file in the court the transcript of the proceedings and the record on which the Administrator based his order;
>
> (g) A certified copy of the transcript of the record and proceedings shall be furnished by the Administrator to any interested party at his request, and payment of the cost thereof.

(7) Review of the record by a United States Court of Appeals. "The findings of the Administrator as to the facts, if supported by substantial evidence, shall be conclusive."

CONCLUSION

We desire to affirm our support of that part of the proposed legislation referred to in the first paragraph of this report. Our objections to the remaining provisions of the bill are grounded on the tremendous grant of unnecessary power in the hands of the Federal Security Administrator.

LEONARD W. HALL,
JOSEPH P. O'HARA,
JOHN B. BENNETT.

INDIVIDUAL MINORITY VIEW

The undersigned, while concurring in the minority report in opposition to the vast delegation of authority to the Administrator, strongly feels that if this bill is to become law there should be a provision for an appeal and a trial de novo in the United States district court.

Not having had the time to submit my individual views to the other signers of the minority report, I therefore take the responsibility of submitting these additional views.

An appellant who desires a review of the record by a United States court of appeals, is confronted with the law, with reference to the decisions of the Federal Security Administrator, as follows:

> The findings of the Administrator as to the facts, if supported by substantial evidence, shall be conclusive.

The majority of the committee takes the position that the Administrator's action under the bill in listing a drug as "dangerous," thereby limiting it to prescription sale, is subject to judicial review which will assure those affected against abuse of the power granted the Administrator.

With this conclusion I vigorously disagree.

The bill provides for judicial review under the familiar "substantial evidence" rule, which permits the courts to overturn administrative action only if the abuse of administrative authority is of a most flagrant character.

In recent years there has been increasing dissatisfaction with the "substantial evidence" rule, under which the findings of fact made by the administrative agency are conclusive if supported by substantial evidence.

The following typical statements by the Supreme Court give an idea as to the limitations under which the courts have operated in reviewing administrative action under the "substantial evidence" rule:

> * * * (The) court * * * will not consider the expediency or wisdom of the order, or whether, on like testimony, it would have made a similar ruling. *Int. Com. Comm.* v. *Union Pacific R. R.*, 222 U. S. 541.
>
> The order of the Commission * * * was not arbitrary but sustained by substantial, though conflicting, evidence. The courts cannot settle the conflict nor put their judgment against that of the rate-making body * * *. *Int. Com. Comm.* v. *Louis. & Nash. R. R.* 227, U. S. 88, 100.

If the record contained any substantial evidence to support the administrative fact findings, the courts often have felt obligated to sustain the administrative action without reference to how heavily such evidence may have been outweighed by the countervailing evidence in the record. Under this limitation the courts cannot set aside administrative action even when it is clearly contrary to the manifest weight of the evidence.

The type of judicial review leaves much too large an area in which the administrative agency has a free hand to exercise, in an unfair

and unjust manner, the power of life and death over important elements of the economic structure of the country.

The majority report strongly suggests that recent Supreme Court decisions (*Universal Camera Corp.* v. *N. L. R. B.* and *Labor Board* v. *Pittsburgh S. S. Co.*) have made a change in the law which insures operation of the "substantial evidence" rule in such manner that full protection will be given by the courts against unjustified administrative action. These cases held that the courts, in determining whether the administrative action is supported by substantial evidence, are under a duty to make that determination after consideration of the whole record before the administrative agency. No one can say at this time whether, or to what extent, these cases will actually change anything so far as scope and character of judicial review is concerned. There is good ground for believing that they merely state what the law always has been. There is nothing in these cases to indicate that the Supreme Court would regard it as proper for a reviewing court to weigh the evidence in the record and, on the basis of its appraisal of the evidence, reach its own independent judgment as to what the administrative action should have been and take appropriate action to insure that the administrative action conforms to the judgment of the court.

Mr. Justice Frankfurter, speaking for the Court in the Universal Camera case, made the following statement which indicates the narrow limits of judicial review under the law as it is interpreted in that case:

> To be sure, the requirement for canvassing "the whole record" in order to ascertain substantiality does not furnish a calculus of value by which a reviewing court can assess evidence. * * * Nor does it mean that even as to matters not requiring expertise a court may displace the Board's choice between two fairly conflicting views, even though the court would justifiably have made a different choice had the matter been before it de novo.

In the opinion of the undersigned, these cases have no important bearing on the fundamental issue here involved.

The bill as introduced would have authorized judicial review of the Administrator's action in a proceeding in the nature of a trial de novo. In the opinion of the undersigned, that type of judicial review would afford a proper judicial check on administrative abuses.

Largely on the basis of testimony presented to the committee by Judge Stephens of the United States Court of Appeals for the District of Columbia, the committee has rejected this proposal of the introduced bill.

To the extent that the testimony criticized provision for a de novo trial in a United States court of appeals, the objections made by Judge Stephens are probably sound, but no convincing argument has been made against providing for de novo review in an appropriate United States district court. It may be true that review by district courts, if provided for in the case of administrative action of every type, would make some increase, to a limited extent, of cases in United States district courts. However, the proposal in the introduced bill did not extend to all cases of administrative action, but only to review of the action of the Federal Security Administrator, under this proposed legislation, in listing a drug as a "dangerous" drug. This would not require any increase in the number of United States district judges, in my opinion. Furthermore, even if it did, that would be a

small price to pay for judicial review which would effectively control abuses in the exercise of the vast administrative power which this bill proposes to grant to the Federal Security Administrator.

The majority report, apparently on the basis of views stated in letters from the Federal Security Administrator and the Deputy Attorney General of the United States, expresses doubts as to the constitutionality of any provision providing for judicial review of the Administrator's action in a de novo proceeding, on the ground that this would seek to have Federal "constitutional" courts exercise an improper function—that is, one which is legislative or administrative in character, and therefore "nonjudicial."

The views expressed in the letters referred to are based upon a decision rendered by the Supreme Court in the General Electric case (281 U. S. 464) which was decided in 1930. That case held that the Supreme Court (being a "constitutional" court, i. e., one which, because created under the judiciary article of the Constitution, can exercise only "judicial" powers) could not be vested with the power to act as a "superior and revising" administrative agency in reviewing a decision of the Court of Appeals of the District of Columbia (which is not a "constitutional" court) in a case, arising under the Radio Act of 1927, in which the latter court had exercised de novo review of action taken by the Federal Radio Commission. This, the court said, was because it could exercise "judicial powers only," and could not "exercise or participate in the exercise of functions which are essentially legislative or administrative."

The argument is that since United States courts of appeals and United States district courts are "constitutional" courts the principle of the General Electric case applies to them, although this specific question has never been judicially decided. However, even if this is so, de novo review of the Administrator's action would not be barred by the principle of the General Electric case. This is because of the difference in the nature of the function which the court would exercise.

In the General Electric case the basic question in issue was whether the public convenience and necessity would be served by granting an application for renewal of a broadcasting license. Under this bill, the question in issue would be whether a particular drug is—

> because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use * * * (determined) * * * on the basis of opinions generally held among experts qualified * * * to evaluate the safety and efficacy of such drug * * * to be safe and efficacious for use only after professional diagnosis by, or under the supervision of, a practitioner licensed by law to administer such drug.

It will be seen at a glance that the bill calls for the application of a standard, or test, which is not of the same character as that involved in the General Electric case. The latter case called for the exercise of broad judgment and discretion in deciding whether renewal of a broadcasting license would serve "the public convenience and necessity." It is not surprising that the Supreme Court took the view that substitution of its judgment for that of the agency on that question would have involved exercise of a nonjudicial function.

However, under the bill, no similar judgment or discretion would have to be exercised by the court. In applying the standard, or test, provided for by the bill a court would be determining whether a particular drug was or was not included within its terms. The function

of the court would not be essentially different from that exercised by courts every day. It would merely call for application of a statutory standard to the facts of a particular case.

In this connection, it is important to bear in mind that the standard written into the bill is essentialy the same as that now contained in the regulation (prescribed under section 502 (f) of the act) which differentiates "dangerous" drugs (which may be sold only on prescription) from those drugs which (if they bear adequate directions for use) may be safely sold over the counter. In criminal prosecutions, and in seizure and injunction proceedings, involving alleged misbranding, the outsome of the case may depend upon the application by the court to the facts of the case of this standard prescribed in the regulation. If the courts exercise a "judicial" function in applying this standard in criminal, seizure, and injunction actions, how can it be reasonably contended that a court would be called upon to exercise a "nonjudicial" function in applying essentially the same standard in de novo review of the Administrator's action?

Furthermore, it was urged before the committee that this same standard be written into the bill as the basis for case-by-case judicial decision as to which drugs are "dangerous" and which drugs are not. No one suggested that that proposal would have required the courts to exercise a "nonjudicial" function.

The need for trial de novo is emphasized by the narrowness of review of administrative proceedings by the appellate courts. In an increasing number of cases the courts are declaring their impotence to review the findings of fact.

Particularly is this true where the administrative decision is of a quasi-judicial nature, as in the instances of appeals from the Federal Trade Commission, which is a fact-finding body. The courts have repeatedly held that they are bound by the Federal Trade Commission's judgment as to the quality and sufficiency of evidence. Such evidence may consist of biased testimony—*Segal* v. *Federal Trade Commission* (142 Fed. (2d) 255); incompetent evidence—*Bene* v. *Federal Trade Commission* (299 Fed. 468); and the testimony of selected experts—*E. Griffith Hughes, Inc.* v. *Federal Trade Commission* (77 Fed. (2d) 886). In the Segal case the court observed that a part of the testimony was "obviously biased" and said:

> Even so, if the Commission wished to rely upon such testimony, we may not intervene, whatever might be our own indisposition to accept what he said.

The courts refuse on appeal to weigh the evidence. They hold that they are bound by the Commission's findings, if supported by evidence, despite the fact that the weight may be to the contrary. Thus, they need read only the Commission's side of the case and if there is evidence to support the findings, the record to the contrary may be ignored.

The principles of a trial de novo are outlined in my opinion, by Chief Justice D. Lawrence Groner of the Circuit Court of Appeals for the District of Columbia in a letter to the Attorney General—report of the Committee on Administrative Procedure, Seventy-ninth Congress, page 248:

> The correct decision of this question is one of immense importance. It should, in my opinion, be considered by Congress in the light of the real and true purposes which the founders of our Government sought to achieve for themselves and their

posterity. These were free action, free enterprise, free competition. They believed that equal justice between man and man and between citizen and state was one of the impartial rewards which encouraged to efforts that produced great and lasting results. Therefore, they made no provision for exemptions from legal duty. What they did provide for was that there should be no oppression, no exaction by tyranny, no spoliation of private right by public authority, and that there should be a fair, honest, effective government to maintain the things which were thought to be the prerogatives of every individual man.

As in the case of the Federal Trade Commission, the Federal Security Administrator is not only a regulator but he will adjudicate issues of fact between the Government and the citizen as a judicial tribunal. The Administrator, under this bill, will be asked to determine the question of fact of some 30,000 drug items—

because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use * * * (determined) * * * on the basis of opinions generally held among experts qualified * * * to evaluate the safety and efficacy of such drug * * * to be safe and efficacious for use only after professional diagnosis by, or under the supervision of, a practitioner licensed by law to administer such drug.

In the light of the above-quoted section of this bill, the Administrator will be called upon to make decisions of fact "on the basis of opinions generally held among experts qualified." It may be upon the decision of one expert who is opposed by many experts, upon testimony which may be biased or unbiased; and yet, under existing decisions, even if the Administrator made his decision on testimony which was obviously biased, that decision of the Administrator, for all practical purposes, would be final without a trial de novo.

In the light of the Supreme Court decisions and the sweeping scope of the powers granted the governmental administrative agency, unless there is to be complete administrative absolutism, it is obvious that both the Government and the individual should have a "day in court."

JOSEPH P. O'HARA.

○